

correct knowledge and positive attitude especially when they are faced with an emergence of chronic diseases. The aim of this study therefore is to assess the level of Type 2 Diabetes Mellitus (T2DM) awareness and disease related attitude among general population at Bujang Valley, Merbok, Kedah, Malaysia. **METHODS:** A questionnaire based, cross sectional study was conducted. The Diabetes Attitude Scale was used to assess the knowledge and attitude of respondents towards T2DM. Data was described descriptively and SPSS v.22 was used for data analysis. **RESULTS:** Out of three hundred and seventy seven respondents, majority of the respondents (n=156, 41.4%) were in age group of more than 40 years old and the cohort was dominated by Malay ethnic group. Females subjugated over males (n=229, 60.7%) and the highest number of respondents were working as businessman (n=115, 30.5%). Corresponding to the marital status, majority of the respondent were married (n=247, 65.5%). Majority of the respondents (n=274, 72.7%) were reported as healthy with no chronic disease. The respondents reported certain misapprehensions where they believed that T2DM have lesser complications, blood glucose control is needed for Type 1 Diabetes Mellitus only and the emotional effects of T2DM are minor. **CONCLUSIONS:** The study reported insufficient level of knowledge among the respondents in management of T2DM. General population needs to have good collaboration with healthcare professionals to get more education and knowledge related to T2DM for their empowerment.

## PDB99

## A NOVEL TOOL TO MEASURE THE SUBJECTIVE BURDEN OF ACUTE POST-PRANDIAL HYPERGLYCAEMIA (PPHG)

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**OBJECTIVES:** A small but growing body of evidence suggests that acute post-prandial hyperglycaemia (PPHG) can have a significant impact on some people with diabetes. This study was designed to develop a standardised tool to measure the impact of PPHG episodes. **METHODS:** Twenty-four adults ( $\geq 18$  yrs) with Type 1 (n=14) and Type 2 (n=10) insulin-dependent diabetes took part in a qualitative study to describe the experience and impact of PPHG. Data were collected via one-to-one telephone interviews in the US (n=10) and two focus groups in the UK (n=14). Thematic analysis was conducted on the transcripts to identify emerging themes. Themes were drawn into measurement domains and described in terms of specific items. The study protocol was approved by an ethics review board. **RESULTS:** The qualitative analysis identified 7 clear domains which could be grouped into two larger groups. The first 4 domains (25 items) relate to participants' most recent spike in blood sugar within the last 2 weeks (How I felt; Thinking and Concentration; Work; Awareness). The remaining 3 domains (22 items) relate more generally to the experience of PPHG after eating (Preventative Behaviours; Worry and Concerns; Management). **CONCLUSIONS:** The qualitative research identified a range of different ways that people can be affected by acute PPHG. This is reflected in the domains of the new measure. Further validation and testing is required and this is planned in a quantitative study involving 800 participants in the UK and US. This measure, when finalised, will allow us to better understand the impact and burden of acute PPHG.

## PDB100

## BENEFITS AND RISKS OF VILDAGLIPTIN/METFORMIN VERSUS SULPHONYLUREAS/METFORMIN COMBINATION THERAPY IN TYPE 2 DIABETES MELLITUS (T2DM) FROM PATIENT'S PERSPECTIVE: REAL-WORLD DATA

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**OBJECTIVES:** Patient-reported outcomes is an effective way to evaluate risks/benefits of antidiabetic treatment in patients with T2DM and has been increasingly considered in treatment decision-making. The goal of this multicenter observational study was to evaluate quality of life (QoL) and hypoglycemia burden in T2DM patients receiving oral combination therapy in a real-world setting. **METHODS:** A total of 160 T2DM patients receiving vildagliptin plus metformin (mean age 59.6 yrs; male/female 25/57) or sulphonylureas (SU) plus metformin (mean age 65.1 yrs; male/female 23/55) for at least 6 months (mean 6.5 yrs, 0.6–17 yrs) were enrolled in the study. All the patients completed the QoL questionnaire SF-36 and the Hypoglycemia Perspectives Questionnaire. Integral QoL Index (IQoLI) was calculated on the basis of SF-36. Group comparisons were made using  $\chi^2$  test and analysis of covariance (ANCOVA) with adjustment for age, sex, disease duration, HbA1c level, complications, comorbidities. **RESULTS:** Patients receiving SU plus metformin had worse role physical and role emotional functioning, vitality, social functioning and pain ( $p < 0.01$ ) than those receiving vildagliptin plus metformin; their IQoLI was significantly lower than in the latter group ( $p < 0.05$ ). They exhibited more pronounced QoL impairment as compared to those receiving vildagliptin plus metformin ( $p = 0.002$ ). 50% patients on SU plus metformin vs 27% patients on vildagliptin plus metformin experienced hypoglycemia during the last 6 months ( $p < 0.003$ ). In the group on SU plus metformin 9.6% patients had severe hypoglycemia and 4.1% – nocturnal hypoglycemia; patients on vildagliptin plus metformin – only non-severe hypoglycemia and no nocturnal hypoglycemia episodes. SU plus metformin therapy was accompanied with pronounced hypoglycemia burden as compared to vildagliptin plus metformin therapy. **CONCLUSIONS:** Results of this real-world study demonstrate benefits of vildagliptin plus metformin combination therapy in T2DM patients as compared to SU plus metformin therapy in terms of better QoL and lower risks of treatment in terms of less hypoglycemia burden.

## PDB101

## DIAREG - DIABETES REGISTER INCLUDING PATIENT REPORTED OUTCOMES

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**OBJECTIVES:** The approach of the diabetes register named DIAREG is to display the health care reality of patients with type 2 diabetes (T2D) in Germany. In comparison to other existing diabetes registries, DIAREG analyses patient-reported outcomes (PRO) in order to illustrate patient reported quality of life (QoL). **METHODS:** In July 2013 DIAREG was started including retrospective as well as prospective data from over 100 office based physicians (general practitioner and diabetologists). DIAREG analysis is based on 6 different PRO: generic quality of life questionnaire (SF-36); audit of diabetes-dependent quality of life (ADDQoL); diabetes treatment satisfaction questionnaire (DTSQ); impact of weight quality of life (IWQoL-Lite); Center of Epidemiological Studies Depression Scale (CES-D) and WHO five well being index (WHO-5). **RESULTS:** By June 2015 more than 2,000 T2D patients were included in the register, involving an observation period of 22 months. Within this time frame PRO of more than 300 patients were completed. The mean age of T2D patients was 68.5 years, whereas 48% of the patient population was older than 70 years. According to a subgroup analysis of 1,646 patients, 16% of the patients were recruited by office-based diabetologists and the majority of 84% by primary care physicians. About 20% of these patients had their therapy changed within the last year due to inadequate HbA1C control. An adjustment of the current therapy was conducted at 81%, a change of the therapy at 46%. Main focus of the physicians for changing the therapy pattern was the decrease of the HbA1C. Based on this platform, further evaluation on QoL will be started. **CONCLUSIONS:** In conclusion, DIAREG shows the treatment reality from the patient and physician perspective and will therefore describe the health care situation and QoL of diabetes patients in Germany.

## PDB102

## RASCH ANALYSIS IN THE DEVELOPMENT OF A SPECIFIC HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE FOR HYPOGLYCEMIC EVENTS IN DIABETIC PATIENTS: THE QOLHYPO QUESTIONNAIRE

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**OBJECTIVES:** To develop a specific questionnaire to assess the impact of hypoglycemia on the health-related quality of life (HRQoL) of patients with type 2 diabetes mellitus (T2DM). **METHODS:** A first version of the QoLHypo questionnaire was obtained from a literature review and focus groups with patients and physicians. QoLHypo consisted of 37 specific items about the impact of hypoglycemia on HRQoL with 5 response categories. The final version was obtained by item reduction methods: floor and ceiling effects and Rasch analysis. Rasch methodology allowed obtaining a questionnaire which responses will be a trade-off between respondent's abilities and item difficulty. Rasch assesses the appropriateness of item responses with probability curves that must appear ordered as the response categories. Overlapped categories suggested excess of response options and were reduced and items with disordered categories were eliminated. The goodness of fit of items in the Rasch model was calculated using the normalized Infit and Outfit statistics whose interval of good fit is (-2, 2). Items with statistics falling outside that interval were removed. Analyses were performed on a sample of 140 patients. **RESULTS:** 55.0% of patients were men, aged 63.0 (mean)(SD:9.6) years. Patients had 14.6 (mean)(SD:6.9) years of T2DM duration and 5.5 (mean)(SD:11.1) hypoglycemic events in the previous 6 months. 11 items were deleted because of floor and ceiling effect. Most of probability curves showed overlapping response categories; therefore two pairs of categories were joined. Probability curves were represented again and 11 items that showed disordered categories were eliminated. Goodness of fit of the 15 remaining items showed only 2 items not adjusting to the model that were deleted. The final version of QoLHypo consisted of 13 items with 3 response categories. **CONCLUSIONS:** Rasch analysis has led to obtain a reduced questionnaire for measuring how hypoglycemia affects the HRQoL in T2DM patients.

## PDB103

## TRANSLATION AND VALIDATION OF THE POLISH DIABETIC FOOT ULCER SCALE - SHORT FORM (DFS-SF)

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**OBJECTIVES:** Diabetic foot ulcer (DFU) is a common complication of diabetes and not only an important factor of mortality among patients with diabetes but also a cause of decreased quality of life. The Diabetic Foot Ulcer Scale (DFS) and short form of the DFS (DFS-SF) provide comprehensive measurement of the impact of diabetic foot ulcers on patients' QoL. The purpose of this study was to translate DFS-SF into Polish and evaluate its psychometric performance in patients with diabetic foot ulcers. **METHODS:** DFS-SF translation process was performed in line with Principles of Good Practice for the Translation and Cultural Adaptation Process for PROMs developed by ISPOR TCA group. Assessment of the reliability and validity of Polish DFS-SF was performed in native Polish patients with current DFU. The severity of ulcers was evaluated using the PEDIS scale. For each scale, the item convergent validity and discriminant validity was computed. Internal consistency of each subscale was examined using the Cronbach's alpha coefficient. Inter-scale validity was examined by Spearman's rank correlation coefficient between DFS-SF and SF-36v2. **RESULTS:** The DFS-SF validation study involved 212 patients diagnosed with DFU, with 4.4 years of DFU duration on average. The average ulcer size was 7.0 sq cm, and generally only one limb was affected. Men (72%) and type 2 diabetes patients (86%) prevailed, with 17.8 years representing the mean time since diagnosis. The mean population age was 62.5 years. The internal consistency of all scales of the Polish DFS-SF was high (Cronbach's alpha ranged from 0.83 to 0.94). Item convergent and discriminant validity was satisfactory (median corrected item-scale correlation ranged from 0.61 to 0.81). The Polish DFS-SF demonstrated good construct validity when correlated with the SF-36v2. **CONCLUSIONS:** The newly translated Polish DFS-SF may be used to assess the impact of DFU on HRQoL in Polish patients.